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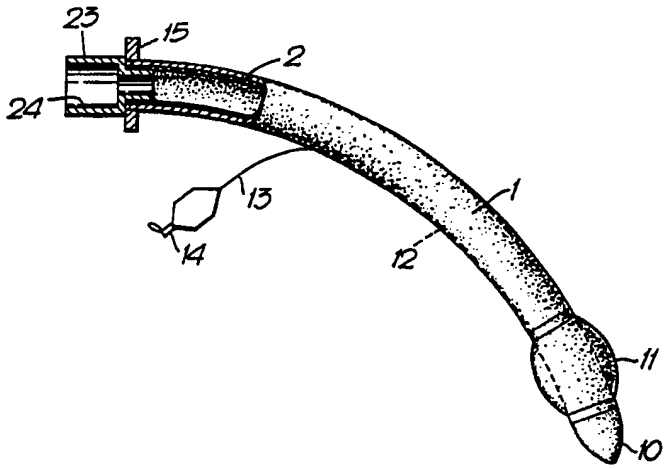
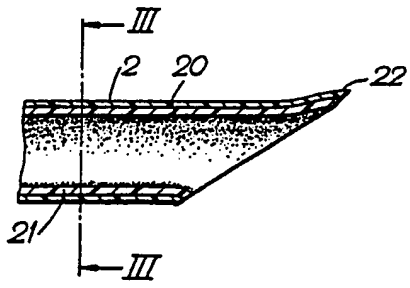
(54) Title: TRACHEAL TUBE ASSEMBLIES





(57) Abstract

A tracheal tube assembly has an outer tube (1) and an inner cannula (2) with a patient end (22) that is flared outwardly to a diameter greater than the internal diameter of the outer tube. When inserted in the outer tube, the patient end of the inner cannula is deformed inwardly and forms a wiping seal. The remainder of the inner cannula (2) has an external diameter less than the internal diameter of the outer tube (1) so that it is readily inserted. The inner cannula may be coextruded with an outer layer (20) of a low friction material such as a polyolefine.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9100235 SA 44850

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 17/06/91 The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A- 0037719	14-10-81	US-A- 4315505	16-02-82
		EP-A,B 0107779	09-05-84
		JP-C- 1319053	29-05-86
		JP-A- 57006652	13-01-82
		JP-B- 60040306	10-09-85
US-A- 2923299		None	

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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Tracheal tube assemblies.

This invention relates to tracheal tube assemblies of the kind having an outer tube an inner cannula that is insertable within and removable from the outer tube.

With such assemblies, the inner cannula is removed and replaced periodically when secretions have built up on the cannula to an extent that there is a risk of blockage. Tracheal tube assemblies are described, for example, in US 3948274, GB 2056285B, GB 1099277, GB 125754, WO 90/04992, FR 2539998A, DE 72467, DE 1268313, EP 0107779A, US 4817598, US 3659612, US 4009720, US 3088466, US 4315545, US 2765792, US 3169529, US 3263684, US 3334631, US 3587589, US 3688774, US 3731692, US 3889688, US 3948273, US 3973569, US 3987798, US 4033353, US 4045058, US 4235229, US 4471776, US 4593690.

The inner surface of tracheal tubes, in use, tends to accumulate a film of respiratory secretions and bacteria. This film can obstruct the bore of the tube and reduce gas flow along it. It has been found that the film can also act as a site for build up of bacteria in quantities sufficient to cause infection if dislodged from the tube and subsequently inhaled. The use of an inner

cannula which is periodically removed and replaced, can reduce these effects but brings with it disadvantages. In particular, the thickness of the wall of the inner cannula will itself reduce the effective bore of the tube. This can be mitigated by making the external diameter of the inner cannula as close as possible to the internal diameter of the tube and making the cannula wall is as thin as possible in order to maximize the diameter of the gas passage through the tube assembly. It is also important to prevent passage of secretions between the outside of the cannula and the inside of the outer tube. A close fitting inner cannula can, however, be difficult to insert because of friction with the bore of the tube. This can make inner cannula prone to kinking, especially if the wall of the cannula is thin. This difficulty is aggravated by the fact that the inner cannula is preferably made of material to which secretions will cling without becoming dislodged into the bronchii and that these materials, such as PVC, tend to have a relatively high coefficient of friction. These materials also tend to be relatively flexible, so that the cannula wall must be made thick enough to prevent kinking on insertion.

It is an object of the present invention to provide an improved tracheal tube assembly.

According to the present invention there is provided a tracheal tube assembly of the above-specified kind, characterised in that the inner cannula has at its patient end an external diameter that is greater than that of the major part of the inner cannula, that the external diameter at the patient end is at least equal to the internal diameter of the outer tube such that the inner cannula seals with the outer tube at its patient end, and that the external diameter of the major part of the inner cannula is less than the internal diameter of the outer tube so that the inner cannula is freely insertable along the outer tube.

The patient end of the inner cannula is preferably deformable radially, before insertion in the outer tube the external diameter of the patient end of the inner cannula being greater than the internal diameter of the outer tube. The inner cannula is preferably flared outwardly at the patient end and may be of a plastic material. The inner cannula may have an inner surface to which respiratory secretions will cling and an outer surface of a different material with a lower coefficient of friction than the inner surface. The inner surface may be of PVC and the outer surface of polyolefine. The patient end of both the inner cannula and the outer tube may be bevelled.

An endotracheal tube assembly in accordance with the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a sectional side elevation of a part of the assembly;

Figure 2 is an enlarged side elevation section of a part of the assembly; and

Figure 3 is a transverse sectional view along the line III - III of Figure 2.

The assembly comprises an outer endotracheal tube 1 of conventional construction and an inner cannula 2 which is insertable in, and removable from, the outer tube.

The outer tube 1 is of a constant radius curvature along its length and is made of PVC or a similar plastics material. At its forward, patient end, the tube 1 has a bevelled, open tip 10 which, in use, is located in the trachea of the patient. Close to the forward end, a cuff 11 embraces the tube which is inflatable via a lumen 12 extending along the wall of the tube which communicates with an inflation line 13 and connector 14. A flange 15 is connected to the rear, machine end of tube 1 where it emerges from the mouth of the patient.

The inner cannula 2 is of the same length as the outer tube 1 and in preformed with the same curvature. The inner cannula 2 is a coextrusion of two different materials. More particularly, the outer layer 20 is of a relatively low friction plastics material such as a polyolefine, for example, a low density polyethylene or polypropylene. The inner layer 21 is of a material with a higher coefficient of friction but which enables respiratory secretions and bacteria to cling to it. In this respect, the inner layer 21 may be of the same material as the outer tube 1, namely PVC. Various

different factors determine the degree to which secretions will cling to the inner layer 21. For example, a highly polar material will improve adhesion as will the presence of microscopic surface formations. A hydrophilic material may also provide a better site for adhesion of the secretions.

The outer layer 20 is more rigid that the inner layer 21 which is relatively flexible.

The inner cannula 2 is of circular shape and of the same external diameter along the major part of its length, which is slightly less than the internal diameter of the outer tube. The clearance between the inner cannula and the outer tube is sufficient to enable the inner cannula to be freely inserted and removed without substantially reducing the internal diameter and hence the gas passage through the assembly. Insertion is further facilitated by the low friction outer surface of the cannula.

At its patient end, the cannula 2 is flared outwardly to form a portion 22 which, in its natural state, before insertion in the outer tube 1, has an external diameter slightly greater than the internal diameter of the outer tube.

At its machine end, the cannula 2 has a coupling 23, the forward end of which mates with the machine end of the outer tube 1. The rear end of the coupling is provided with a female luer tapered recess 24 that is adapted to receive a cooperating coupling (not shown) connected to a patient ventilator.

In use, the forward end of the inner cannula 2 is pushed into the machine end of the outer tube 1, the bevel at the forward end of the cannula serving to aid initial insertion into the tube. The deformable nature of the inner cannula allows its forward portion 22 to be deformed inwardly by contact with the inside of the tube. In this way, the portion 22 forms a sliding, wiping seal with the tube 1 as it is pushed along it. The friction produced by contact of the portion 22 with the tube 1 is relatively small because of the small area of contact, so that there is little impediment to insertion. When fully inserted, the forward portion 22 of the inner cannula is a close, sealing fit with the bore of the tube 1 at its patient end. In this way, there is little risk of secretions passing between the inner cannula 2 and the outer tube 1.

The nature of the inner surface 21 of the cannula 2 is such that respiratory secretions and bacteria will readily cling to it with only a low risk of dislodgement.

The inner cannula 2 is periodically removed, when accumulated secretions have built up, and replaced by a new cannula, without the need to remove the outer tube. The inner cannula 2 is removed at least once every twelve hours and preferably more frequently, such as every six hours. Conveniently, the cannula is replaced once every time there is a change in shift of nursing staff. Previously, inner cannulae have been replaced only when secretions have reached the stage of threatening to block passage through the assembly, such as, once a day, or every other day. The importance of more frequent replacement in reduced bacterial infection has not heretofore been appreciated.

Because the outer layer 20 of the inner cannula 2 is of a more rigid material than the inner layer 21, it enables the cannula to be made with a thinner wall than would be possible if it were made entirely from the material of the inner layer, and without the risk of the cannula kinking on insertion.

It will be appreciated that the inner cannula 2 need not be a coextrusion but that the inner or outer surface could be provided by treating or coating with a different material. The assembly could be a tracheostomy tube assembly instead of an endotracheal tube assembly.

CLAIMS

1. A tracheal tube assembly having an outer tube and an inner cannula that is insertable within and removable from the outer tube, characterised in that the inner cannula (2) has at its patient end (22) an external diameter that is greater than that of the major part of the inner cannula, that the external diameter at the patient end is at least equal to the internal diameter of the outer tube (1) such that the inner cannula (2) seals with the outer tube (1) at its patient end (10) and that the external diameter of the major part of the inner cannula (2) is less than the internal diameter of the outer tube (1) so that the inner cannula (2) is freely insertable along the outer tube.

2. A tracheal tube assembly according to Claim 1, characterised in that the patient end (22) of the inner cannula (2) is deformable radially, and that before insertion in the outer tube the external diameter of the patient end (22) of the inner cannula (2) is greater than the internal diameter of the outer tube 1.

3. A tracheal tube assembly according to Claim 1 or 2, characterised in that the inner cannula (2) is flared outwardly at the patient end (22).

4. A tracheal tube assembly according to anyone of the preceding claims, characterised in that the inner cannula is of a plastics material.

5. A tracheal tube assembly according to any one of the preceding claims, characterised in that the inner cannula (2) has an inner surface (21) to which respiratory secretions will cling, and an outer surface (20) of a different material with a lower coefficient of friction than the inner surface.

6. A tracheal tube assembly according to Claim 4 or 5, characterised in that the inner surface (21) is of PVC.

7. A tracheal tube assembly according to any one of Claims 4 to 6, characterised in that the outer surface is of a polyolefine.

8. A tracheal tube assembly according to any one of the preceding claims, characterised that the patient end of both the inner cannula (2) and the outer tube (1) are bevelled.

Fig.1.

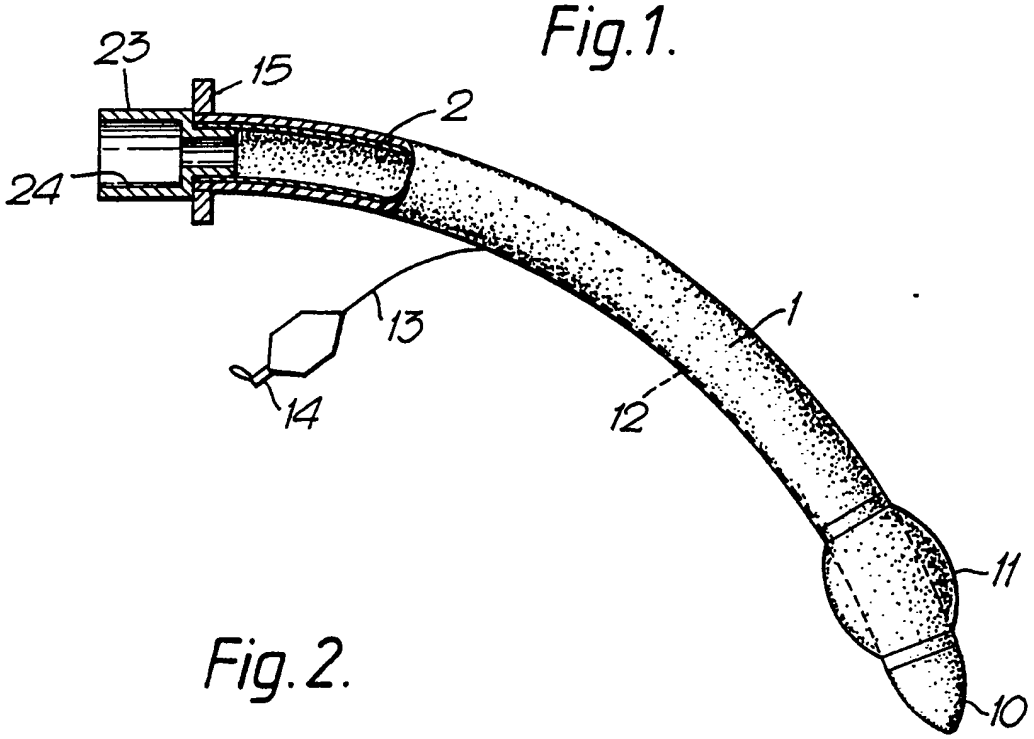


Fig.2.

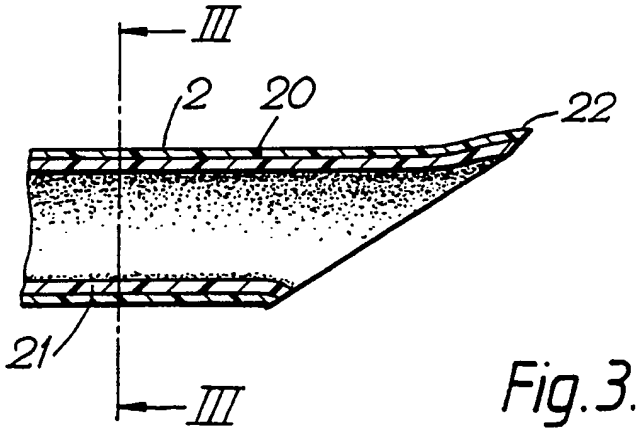
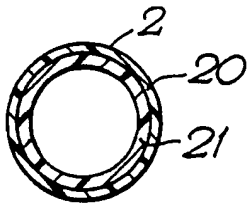


Fig.3.



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 91/00235

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [8]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[5]: A 61 M 16/04

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[5]	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category [10]	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	EP, A, 0037719 (SHILEY) 14 October 1981 see page 3, line 35 - page 4, line 28; page 10, lines 18-22; page 11, lines 26-34; figures 1,3 ---	1,4,6
A	US, A, 2923299 (BLACKWOOD) 2 February 1960 see column 2, lines 23-26; figures 2,5 ----------	5

* Special categories of cited documents: [10]

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15th April 1991	11. 07. 91
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EUROPEAN PATENT OFFICE	F.W. HECK

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